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Tension-Free Vaginal Tape Versus Transobturator Suburethral Tape: Five-Year Follow-up Results of a Prospective, Randomised Trial

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Abstract

Background: Many studies have assessed the equivalent effectiveness of tension-free vaginal tape (TVT) and transobturator suburethral tape (TVT-O) at short- to medium-term follow-up, but no long-term randomised trials appear in the literature.
Objective: We compared the use of TVT to TVT-O, providing a longer follow-up than currently appears in the literature.
Design, setting, and participants: Seventy-two consecutive patients affected by stress urinary incontinence (SUI) were included in this randomised, controlled trial. Patients were randomly allocated to the TVT or TVT-O procedure using a predetermined, computer-generated randomisation code.
Intervention: After preoperative assessment, patients were randomly allocated to the TVT or TVT-O procedure.
Measurements: This 5-yr study represents the extension of our original randomised trial, which was designed to assess the incidence of long-term complications (primary end point) and successes (secondary end point) for both techniques.
Results and limitations: At 60-mo follow-up, 52 patients (72%) were objectively cured of SUI (72.9% after TVT-O and 71.4% after TVT), but only 44 patients (61%) were satisfied. The late complication rate was 16.6% (10 women): five women (16.1%) in the TVT-O group and five women (17.2%) in the TVT group ($p = 1$). In this follow-up, 62% of the patients from the TVT-O group and 60% from the TVT group ($p = 1$) expressed that they were satisfied or very satisfied with the results. The mean cause of dissatisfaction was the development of sexual dysfunction resulting from dyspareunia or incontinence during intercourse, which was found in 6 of 16 dissatisfied patients (37.5%). The limitations of our study included the adequate but small sample size and the lack of questionnaires.
Conclusions: Both surgical techniques are safe, with similar results (72.9% and 71% of patients objectively cured after TVT-O and TVT, respectively) and low complication rates (16.6%: 16.1% and 17.2%, respectively, for TVT-O and TVT), even after 5-yr follow-up.

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1. Introduction

Urinary incontinence is a common problem that affects adult women [1]; the predominant form is the stress type (50%). Tension-free vaginal tape (TVT) is the most popular and effective procedure to correct urinary incontinence, with a high score of self-reported satisfaction and an objective cure rate >80% at 7 yr after surgery [2]—similar to the Burch colposuspension cure rate [3]. Despite the high success rate reported, however, patients can be exposed to several complications. To avoid complications related to the blind passage of the tape through the retropubic space, such as bladder or bowel perforation, the transobturator route was introduced by Delorme in 2001 [4,5] and subsequently modified by de Leval [6].

Several randomised, controlled trials (RCT) in the literature have assessed the equivalent effectiveness of inside, inside-out, and outside-in tapes as well as TVT with short- to medium-term follow-up, as reported by two recent meta-analyses [7,8]. We have already published a prospective, randomised study comparing TVT and transobturator suburethral tape (TVT-O) for the treatment of stress urinary incontinence (SUI) at 12 mo, finding no differences in effectiveness between TVT and TVT-O [9]. The purpose of the current study is to report the incidence of 5-yr complications (primary end point) and successes rates (secondary end point) of our original randomised trial.

2. Materials and methods

We used CONSORT criteria in the description of this trial. As described in the original report of this study, from July 2004 to May 2005, we included consecutive patients affected by SUI. A detailed description of the methods was previously published, including surgical procedures, inclusion and exclusion criteria, ethical approval, and postoperative evaluation [9].

In this study, we evaluated patients' status through a urogynaecologic exam and a stress test every year. Furthermore, a urogynaecologic interview was recorded at the fifth year of follow-up during which we asked questions about symptoms, voiding habits and pelvic pain, dyspareunia, and incontinence during sexual intercourse; provided a visual analogue scale (VAS) for subjective cure rate; conducted a clinical examination with cotton swab, cough stress test, Pelvic Organ Prolapse Quantification (POP-Q) system evaluation; and made a urodynamic assessment. After 60 mo, patients were asked to describe their overall satisfaction using three simple, standardised questions: (1) "Are you satisfied by the results of the surgery? You can choose between the

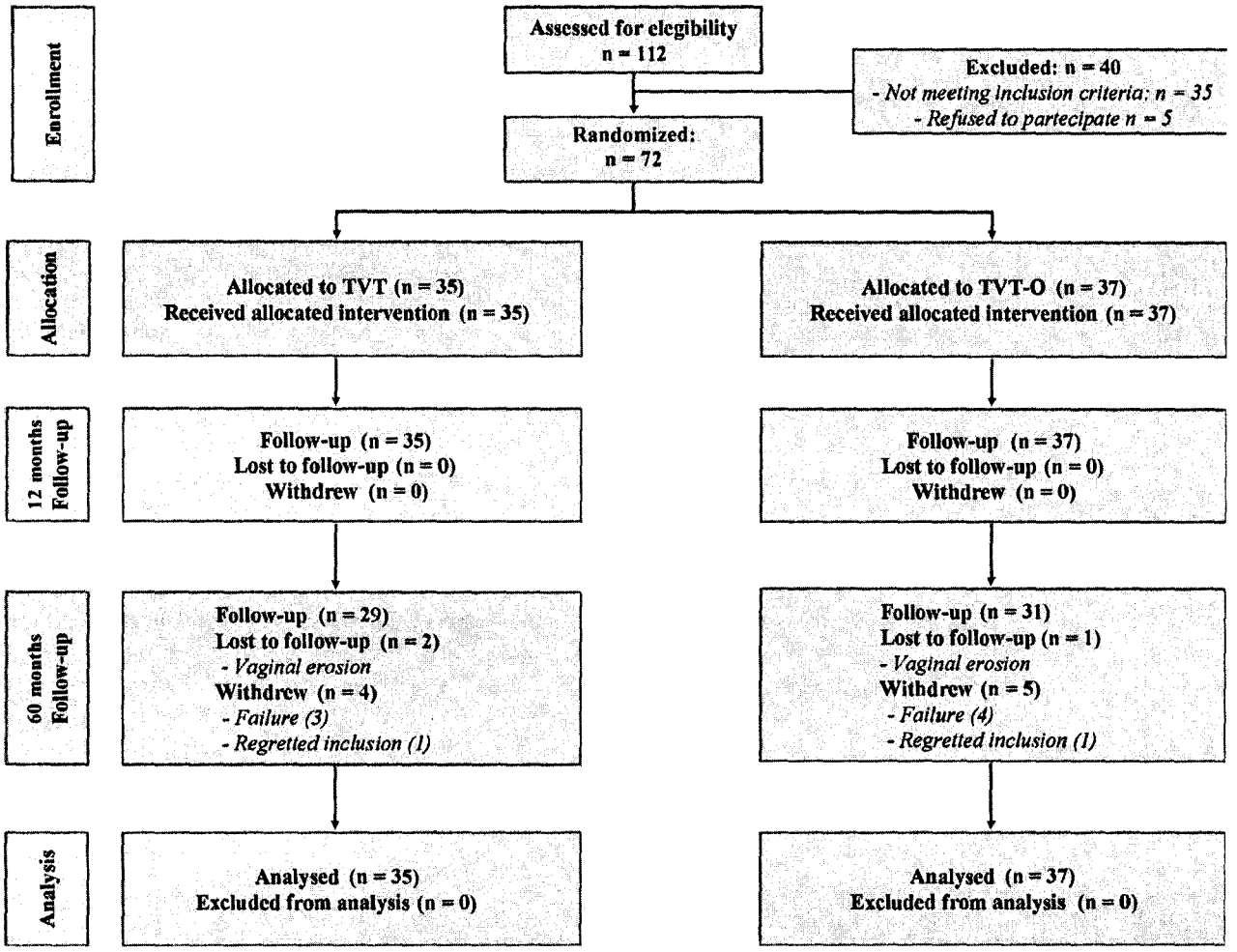

Fig. 1 – CONSORT flow diagram for patients who were brought into the trial.
TVT = tension-free vaginal tape; TVT-O = transobturator suburethral tape.

Table 1 – Preoperative and 5-yr follow-up urogynaecologic clinical examination

	TVT-O		p value	TVT		p value
	Baseline	5-yr		Baseline	5-yr	
Cotton swab test (mean ± SD)*	72.6 ± 29.2	36.2 ± 12.4	0.0001	78.4 ± 42.4	35.1 ± 7.1	0.0001
Positive stress testing, no. (%)**	37 (100)	4 (10.8)	0.0001	35 (100)	4 (14)	0.0001
POP-Q system***						
Stage 0, no. (%)****	11 (30)	8 (26)	0.79	9 (26)	6 (20)	0.77
Stage 1, no. (%)****	24 (65)	25 (79)	0.18	25 (71)	23 (80)	0.56
Stage 2, no. (%)	0	0	–	0	0	–

TVT-O = transobturator suburethral tape; TVT = tension-free vaginal tape; SD = standard deviation; POP-Q = Pelvic Organ Prolapse Quantification system.
* Comparisons within groups was not statistically significant ($p = 0.481$).
** Comparisons within groups was not statistically significant ($p = 1$).
*** POP-Q stage is related to urethrocele.
**** Comparisons within groups was not statistically significant ($p = 0.77$).

following answers: Very satisfied, Satisfied, or Not satisfied"; (2) "Would you repeat the same procedure if SUI recurred"; and (3) "Do you recommend the same procedure to other patients?"

We considered all the complications that developed after the first year of follow-up as "late complications." *Dyspareunia* was defined as pain during sexual intercourse and was assessed with the following question: "Did you experience pain during sexual intercourse?" *Chronic pelvic pain* was defined as a nonmenstrual pain lasting ≥6 mo that was localised in the pelvis, lower abdominal wall, or lower back and severe enough to require medical care. *Cure of SUI* was defined as the lack of urinary leakage during stress test at urodynamic control.

The primary outcome measures at 60 mo were long-term complication rates; the development of voiding problems or urgency; and subjective cure, with the overall satisfaction of the patients measured by the VAS and with simple, standardised questions. The secondary outcome measure was the objective cure of stress incontinence, defined as the absence of urinary loss during the cough stress test. The sample size was calculated according to the incidence of intraoperative and postoperative complications and has been reported previously [9].

Patients were randomly allocated to the TVT or TVT- O procedure using a predetermined, computer-generated randomisation code. The present study was not blinded, but all follow-up examinations were performed by physicians not involved in the study protocol (masked).

The Wilcoxon signed rank sum test and the Mann-Whitney *U* test were used for comparisons within groups. Changes in urinary symptoms from baseline were analysed using the McNemar test, with the Fisher exact test used for analysis between groups. Statistical significance was set at $p < 0.05$. Further analysis was carried out by testing different assumptions about withdrawals and losses to follow-up using the Fisher exact test.

3. Results

Seventy-two consecutive patients affected by SUI (37 in the TVT-O group and 35 in the TVT group) were included in this RCT. Their progress through the trial is shown in Fig. 1. All patients were examined at 12 mo follow-up, while 12 patients did not return for 5-yr follow-up—three patients were lost (two in the TVT group and one in the TVT-O group), and nine patients withdrew (four in the TVT group and five in the TVT-O group). Median follow-up was 60 mo (range: 13–69; interquartile range: 2.5).

The overall objective success rate was 72.2% (52 women), with 27 patients treated with TVT-O (72.9%) and 25 with TVT (71.4%; $p = 1$). Furthermore, 12 of the 20 failed patients underwent additional surgery for stress incontinence (10 bulking agent and 2 minisling). The value of cotton swab testing, positive stress testing, and peak flow showed a significant reduction in both groups from baseline to 12-mo follow-up visit ($p < 0.01$), but there were no statistically significant differences between 12 and 60 mo (Table 1). There were no differences in the two groups between baseline and 60-mo follow-up for pelvic prolapse or for other urodynamic data (Table 2).

The late complication rate was 16.6% (10 women)—five patients in either group (16.1% for TVT-O and 17.2% for TVT; $p = 1$). Main late postoperative complications were de novo urgency, dyspareunia, and incontinence during intercourse. De novo urgency occurred in three patients (5%)—two (6.4%) in the TVT-O group and one (3.4%) in the TVT group (Table 3). Dyspareunia and incontinence during intercourse occurred in 2 (5.1%) and 4 (10.2%), respectively, of the 39 sexually active women (65%) who completed follow-up, equally divided between the two groups (Table 4).

Table 2 – Preoperative and 60-month postoperative urogynaecologic clinical examination and urodynamic evaluation

Urodynamic assessment	Baseline	At 60 mo	p value
Peak flow, ml/s*			
TVT-O, mean ± SD	26.6 ± 5.5	22.7 ± 3.4	0.0010
TVT, mean ± SD	25.8 ± 6.3	21.8 ± 3.3	0.0031
Maximum cystometric capacity, ml**			
TVT-O, mean ± SD	473 ± 56	483 ± 55	0.46
TVT, mean ± SD	468 ± 49	473 ± 52	0.69
Detrusor pressure at peak flow, cm H_2O***			
TVT-O, mean ± SD	18.2 ± 7.2	16.2 ± 8.1	0.28
TVT, mean ± SD	17.3 ± 7.9	16.8 ± 5.8	0.78
MUCP, cm H_2O****			
TVT-O, mean ± SD	59.4 ± 8.2	61.2 ± 9.2	0.39
TVT, mean ± SD	55 ± 8.5	57.6 ± 8.3	0.23

TVT-O = transobturator suburethral tape; SD = standard deviation; TVT = tension-free vaginal tape; MUCP = maximal urethral closing pressure.
* Comparisons within groups were not statistically significant ($p = 0.23$).
** Comparisons within groups were not statistically significant ($p = 0.457$).
*** Comparisons within groups were not statistically significant ($p = 0.44$).
**** Comparisons within groups were not statistically significant ($p = 0.06$).

Table 3 – Comparison between groups in relation to urinary symptoms†

	Frequency			Urgency			Nocturia			DO		
	TVT-O	TVT	p	TVT-O	TVT	p	TVT-O	TVT	p	TVT-O	TVT	p
Baseline*	0	0	–	0	0	–	0	1 (3%)	0.49	0	0	–
12 mo*	0	2 (6%)	0.23	0	3 (9%)	0.11	0	0	–	0	0	–
24 mo*	0	0	–	0	0	–	0	0	–	0	0	–
48 mo**	0	0	–	1 (3%)	1 (3%)	1	0	0	–	1 (3%)	1 (3%)	1
60 mo**	0	0	–	2 (6%)	1 (3%)	1	0	0	–	1 (3%)	1 (3%)	1

DO = detrusor overactivity; TVT-O = transobturator suburethral tape; TVT = tension-free vaginal tape.
† Some patients had more than one symptom. Values are numbers of patients with percentages.
* In 72 patients (35 TVT and 37 TVT-O).
** In 60 patients (29 TVT and 31 TVT-O).

Table 4 – Long-term complications

Complication	TVT-O, no.	TVT, no.	p value
De novo urgency	2	1	1
Urinary retention	0	0	–
Chronic pelvic pain	0	1	0.48
Pain during intercourse	1	1	1
Incontinence during intercourse	2	2	1
Vaginal erosions	2	1	1

TVT-O = transobturator suburethral tape; TVT = tension-free vaginal tape.

Tape-related complications were seen in four women—one abscess and three (4%) vaginal erosions (two patients in the TVT group at 15 and 16 mo, and one patient in the TVT-O group at 14 mo). All patients with vaginal erosion required reintervention, with a section or partial removal of the sling, after trying a conservative approach with local oestrogens and antiseptic treatment. Two of these patients became objectively incontinent after partial removal of the sling, but all patients reported an improvement compared to before the first surgery. Fifty-two of 60 women who completed 60-mo follow-up were objectively cured of SUI.

We previously reported a significant improvement in patient satisfaction according to VAS values measuring the severity of urinary incontinence between baseline and 12-mo follow-up [9]. Similar results were reported at the 60-mo evaluation, without differences between 12 and 60 mo (8.2 ± 2.8 vs. 7.9 ± 1.3 for TVT-O and 8.6 ± 3.4 vs. 8 ± 1.2 for TVT).

In this follow-up, 23 patients in the TVT-O group (62%) and 21 in the TVT group (60%; $p = 1$) said that they were satisfied or very satisfied with the results, while 29 patients (78.4%) in the TVT-O group and 22 (62.8%) in the TVT group would undergo the same procedure again if SUI recurred ($p = 0.0756$). The mean cause of dissatisfaction was the development of sexual dysfunction resulting from dyspareunia or incontinence during intercourse, which occurred in 6 of 16 (37.5%) dissatisfied patients. A sensitivity analysis was performed to explore the effect of different assumptions about withdrawals and lost patients (Table 5): No differences were found.

4. Discussion

Despite the large number of trials published on the treatment of SUI [5–25], to our knowledge, the present study is the first RCT that reports 5-yr follow-up data comparing retropubic tape with transobturator tape in the treatment of female SUI. The overall success rate after 5-yr follow-up was 72.2% (72.9% and 71.4% of patients cured after TVT-O and TVT, respectively). This rate seems to be lower compared to the data reported in literature by Latthe and Novara [7,8], but it is because of our longer follow-up and the assumption that all missing data constitute failure.

Furthermore, as shown in Fig. 2, our data demonstrate that the cure rate lasts longer because the majority of failures occurred within the first 12 mo. Therefore, in our opinion, the success of this surgery depends almost exclusively on the tension used; if the tape is correctly positioned, the chance of success is higher, and the result is longer lasting.

Because of the simplicity and minimal invasiveness of this surgery, most of the failure patients agreed to undergo additional surgery for stress incontinence. We performed 10 bulking agent and 2 minisling procedures on the failure patients. Our data confirmed that neither approach constituted an invasive procedure, so that the majority of women—51 patients (85%)—would undergo the same procedure again if SUI recurred, especially within the TVT-O group. This difference, in our opinion, may be the result of the different incidence of postoperative urinary symptoms like frequency and urgency, which could in turn

Table 5 – Sensitivity analysis of different assumptions about withdrawals and lost patients

Assumption	TVT n/N	%	TVT-O n/N	%	OR	95% CI	p value
Assuming all missing data (withdrawals and lost) are failures	25/35	71	27/37	73	0.925	0.32–2.59	1
Assuming all missing data (withdrawals and lost) are cured	31/35	88	33/37	29	0.939	0.21–4.08	1

TVT = tension-free vaginal tape; TVT-O = transobturator suburethral tape; OR = odds ratio; CI = confidence interval.

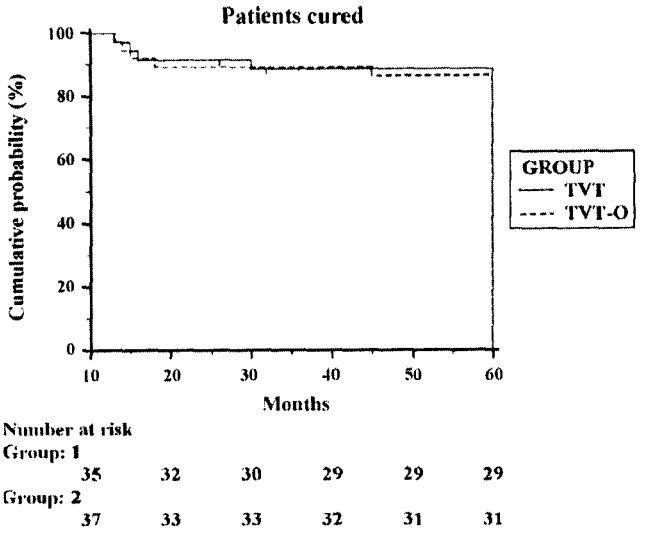

Fig. 2 – Survival analysis comparing tension-free vaginal tape (TVT) and transobturator suburethral tape (TVT-O) for the recurrence of stress urinary incontinence.

be the result of the initial obstructive effect of the sling. We believe that this initial effect is more important in the TVT group because of the U-shaped position of the sling. In fact, as previously published, we found a difference between the two groups with respect to postoperative de novo urgency and frequency in the first 6 mo after surgery [7,8].

The most prevalent complications observed at 5-yr follow-up were de novo urgency symptoms (5%), dyspareunia (3.3%), and incontinence during intercourse (6.6%). The incidence of overactive bladder symptoms such as de novo urgency and frequency, as previously reported, appeared to increase in each group within the first month after surgery and to decrease at 5 yr (as shown in Table 1). Dyspareunia and incontinence during intercourse are key symptoms that affect women's quality of life (QoL). Previous studies have reported that sexual function after anti-incontinence procedures could deteriorate in a not-inconsiderable number of patients—up to 15% [26–29].

Development of sexual dysfunction after midurethral slings seems to be related to incorrect positioning of the sling or to local complications like erosions or abnormal scar formations. TVT-O seems to be associated with a better impact on sexuality, but there are insufficient data to allow the comparison between retropubic and transobturator procedures with respect to sexual activity after surgery. We did not find differences between the two groups regarding sexual function after surgery, but we believe that these complications have a strong impact on QoL. In fact, all six patients with dyspareunia or incontinence during intercourse appeared to be dissatisfied with the outcome of the surgical procedure at the interview at 60-mo follow-up.

Another potential factor that may compromise patient satisfaction after surgery for stress incontinence is the decline in peak urinary flow. This symptom may be caused by excessive tension in the sling, which may in turn cause development of postoperative voiding dysfunctions such as frequency, urgency, and an increased voiding time. Our data did not show a decline in peak flow either group (Table 1).

In our opinion, patient satisfaction is the most important goal of the surgery for urinary incontinence, because this type of surgery is not aimed at saving women's lives but rather at improving their well-being. It is therefore more important to understand whether women's QoL is modified, improved, or worsened, because we can have patients after surgery who are dry but not satisfied. In fact, at 60-mo follow-up, we have 52 women (72%) objectively cured for SUI, but only 44 patients (61%) were satisfied with the surgery (Fig. 3). The mean cause of dissatisfaction was the development of sexual dysfunction after surgery (six patients). Other causes were de novo urgency (one patient), chronic pelvic pain, and failure of the procedure.

The most important tape-related complication was the development of vaginal erosion. Usually, this is a difficult complication for the patient, because she feels pain, especially during intercourse, resulting from a sense of a

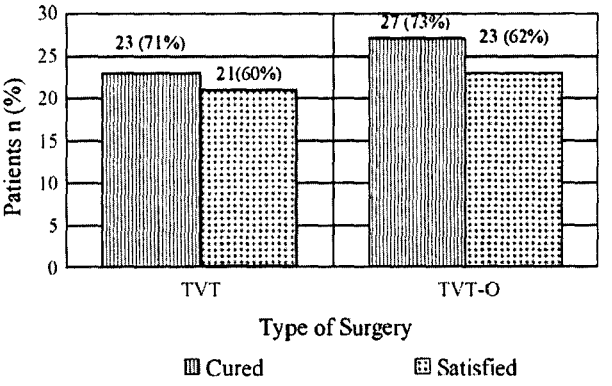

Fig. 3 – Proportion of cured and satisfied patients in the tension-free vaginal tape (TVT) and transobturator suburethral tape (TVT-O) groups at 5-yr follow-up.

foreign body in her vagina. However, in our trial, only one of the three vaginal erosions was symptomatic, while the other two were found during a routine gynaecologic exam. No differences for vaginal erosion were found between the two procedures, as already reported by a recent meta-analysis by Novara et al. [8]. However, we believe that the hammock-shaped orientation of the sling in the transobturator approach could result in a bigger contact area with the vagina than the retropubic (U-shaped) position of the TVT, with a greater inflammation and erosion rate.

Regarding the potential bias of the present study, the major limitations could be the small sample size (originally calculated on the incidence of intraoperative and postoperative complications, which are our primary end point) and the lack of a detailed questionnaire to asses the subjective cure rate (because of the absence of validated Italian questionnaires at the beginning of this trial).

5. Conclusions

Our study shows that both surgical techniques have similar results (72.9% and 71% of patients objectively cured after TVT-O and TVT, respectively) and low complication rates (16.6%; 16.1% and 17.2%, respectively, for TVT-O and TVT) even after 5-yr follow-up. The development of complications such as dyspareunia or incontinence during intercourse may cause a reduction patient satisfaction, even in dry patients.

Author contributions: Roberto Montera had full access to all the data in the study and takes responsibility for the integrity of the data and the accuracy of the data analysis.

Study concept and design: Zullo, Angioli, Plotti, Muzii; Benedetti Panici.
Acquisition of data: Montera.
Analysis and interpretation of data: Zullo, Angioli, Muzii.
Drafting of the manuscript: Zullo, Angioli, Plotti, Montera.
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